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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/554,258

01/18/2007

Guy Vergnault

28069-618-NATL

3154

30623

7590

06/22/2010

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EXAMINER

LOVE, TREVOR M

ART UNIT

PAPER NUMBER

1611

MAIL DATE

DELIVERY MODE

06/22/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/554,258	Applicant(s) VERGNAULT ET AL.	
	Examiner TREVOR M. LOVE	Art Unit 1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 May 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2 and 4-14 is/are pending in the application.
- 4a) Of the above claim(s) 9-11 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-8 and 12-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>09/16/2008, 10/24/2005</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Claims 1, 2, 4-14 are pending.

Applicant's election with traverse of Group I (claims 1, 2, 4-8, and 12-14) in the reply filed on 05/04/2010 is acknowledged. The traversal is on the ground(s) that Applicant believes the claims to be directed to a single inventive concept, and therefore, they should be examined together. This is not found persuasive because as seen by U.S. Patent number 3,145,169 (as cited in the restriction requirement), the claims do not all comprise a special technical feature.

The requirement is still deemed proper and is therefore made FINAL.

Claims 9-11 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected Group II, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 05/04/2010.

Claims 1, 4, 6, 10, and 11 are currently amended.

Claims 1, 2, 4-8, and 12-14 are currently under consideration.

NOTE: claim 1 is improperly identified as being "Previously Presented". Said claim should have been identified as "Currently Amended".

Specification

It is noted that this application appears to claim subject matter disclosed in prior Application No. PCT/IB04/01702, filed 4/23/2004. A reference to the prior application must be inserted as the first sentence(s) of the specification of this application or in an application data sheet (37 CFR 1.76), if applicant intends to rely on the filing date of the prior application under

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35 U.S.C. 119(e), 120, 121, or 365(c). See 37 CFR 1.78(a). For benefit claims under 35 U.S.C. 120, 121, or 365(c), the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of all nonprovisional applications. If the application is a utility or plant application filed under 35 U.S.C. 111(a) on or after November 29, 2000, the specific reference to the prior application must be submitted during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. If the application is a utility or plant application which entered the national stage from an international application filed on or after November 29, 2000, after compliance with 35 U.S.C. 371, the specific reference must be submitted during the pendency of the application and within the later of four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) or sixteen months from the filing date of the prior application. See 37 CFR 1.78(a)(2)(ii) and (a)(5)(ii). This time period is not extendable and a failure to submit the reference required by 35 U.S.C. 119(e) and/or 120, where applicable, within this time period is considered a waiver of any benefit of such prior application(s) under 35 U.S.C. 119(e), 120, 121 and 365(c). A benefit claim filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed benefit claim under 35 U.S.C. 119(e), 120, 121 and 365(c). The petition must be accompanied by (1) the reference required by 35 U.S.C. 120 or 119(e) and 37 CFR 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted), (2) a surcharge under 37 CFR 1.17(t), and (3) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Director may require additional information where there is a question whether the delay was

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unintentional. The petition should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

If the reference to the prior application was previously submitted within the time period set forth in 37 CFR 1.78(a), but not in the first sentence(s) of the specification or an application data sheet (ADS) as required by 37 CFR 1.78(a) (e.g., if the reference was submitted in an oath or declaration or the application transmittal letter), and the information concerning the benefit claim was recognized by the Office as shown by its inclusion on the first filing receipt, the petition under 37 CFR 1.78(a) and the surcharge under 37 CFR 1.17(t) are not required. Applicant is still required to submit the reference in compliance with 37 CFR 1.78(a) by filing an amendment to the first sentence(s) of the specification or an ADS. See MPEP § 201.11.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 10/24/2005 and 09/16/2008 have been considered by the Examiner.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 4 are rejected under 35 U.S.C. 102(b) as being anticipated by Spence et al (U.S. Patent number 3,146,169, Patent issued Aug. 25, 1964).

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Spence teaches a tablet with an inert portion that surrounds an active portion (see entire document, for instance column 1, lines 33-36 and Figure IV). Said inert portion and said active portion can comprise the core. Said core is coated by a further outer layer (see entire document, for instance Figure IV and column 3, lines 35-36). Said inert portion comprises components such as barium sulfate or aluminum silicate (see column 1, lines 49-56), this reads on **instant claims 1 and 4**.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out

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the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1 and 4-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Spence et al (U.S. Patent number 3,146,169, Patent issued Aug. 25, 1964).

Spence teaches a tablet with an inert portion that surrounds an active portion (see entire document, for instance column 1, lines 33-36 and Figure IV). Said inert portion and said active portion can comprise the core. Said core is coated by a further outer layer (see entire document, for instance Figure IV and column 3, lines 35-36). Said inert portion comprises components such as barium sulfate, aluminum silicate, or calcium silicate (see column 1, lines 49-56), this reads on **instant claims 1 and 4**. Spence further teaches that aluminum silicate can be present as, for example, 2.8% of the composition (see Example 7 (b) in context of example 1), note that 2.8% is "about" 1.75%, this reads on **instant claim 5**. The claims of Spence directly state that both barium sulphate and aluminum silicate can be utilized as the inert portion (see entire document, for instance, claims 4 and 6). It is further noted that in Example 7(e) in the context of Example 5, the main inert component (calcium silicate) is present as about 1.3% of the composition.

Spence fails to directly teach the instant amount of excipient.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize barium sulphate or aluminum silicate in the place of the calcium silicate in example 7(e) in the context of example 5. One would have been motivated to do so since an express suggestion to substitute one equivalent component or process for another is not

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necessary to render such substitution obvious. In re Fout, 675 F.2d 297, 213 USPQ 532 (CCPA 1982). The selection of a known material based on its suitability for its intended use supported a prima facie obviousness determination in Sinclair & Carroll Co. v. Interchemical Corp., 325 U.S. 327, 65 USPQ 297 (1945). “Reading a list and selecting a known compound to meet known requirements is no more ingenious than selecting the last piece to put in the last opening in a jig-saw puzzle.” 325 U.S. at 335, 65 USPQ at 301.).

Claims 2, 12, and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Spence et al (U.S. Patent number 3,146,169, Patent issued Aug. 25, 1964) as applied to claims 1 and 4-6 above, and further in view of Thurn-Müller et al (U.S. Patent number 5,310,578, Patent issued May 10, 1994).

The teachings of Spence are set forth above under the discussion of claims 1 and 4-6.

Spence further fails to teach the presence of red iron oxide.

Thurn-Müller teaches that red iron oxide, aluminum silicate and calcium silicate are well known examples of pigments (see entire document, for instance, column 2, lines 44-58).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize red iron oxide with the aluminum silicate, barium sulphate, and/or calcium silicate of Spence. One would have been motivated to do so since it is known to combine known products which are performing their known function to arrive at a third composition for the exact same purpose. There would be a reasonable expectation of success since Thurn-Müller teaches that red iron oxide, aluminum silicate, and calcium silicate are known pigment components, and Spence teaches that aluminum silicate, barium sulphate, and calcium silicate are functionally

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equivalent and can be utilized in combination. It is noted that MPEP 2144.05 states: ““It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art.” *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) (citations omitted). See also *In re Crockett*, 279 F.2d 274, 126 USPQ 186 (CCPA 1960); and *Ex parte Quadranti*, 25 USPQ2d 1071 (Bd. Pat. App. & Inter. 1992).

Claims 7, 8, and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Spence et al (U.S. Patent number 3,146,169, Patent issued Aug. 25, 1964) as applied to claims 1 and 4-6 above, and further in view of Guglielmotti et al (U.S. Patent number 6,020,356, Patent issued Feb. 1, 2000).

The teachings of Spence are set forth above under the discussion of claims 1 and 4-6 wherein it is further noted that Spence teaches that “[t]he medicament in the medicated portion may be any desired medicament” (see column 2, lines 32-33).

Spence further fails to teach the presence of prednisone, prednisolone, or methylprednisolone. Spence further fails to directly teach the dose of said prednisone.

Guglielmotti teaches the treatment of several conditions including autoimmune hepatitis, type 1 diabetes, and systemic lupus erythematosus with a combination of bindarit and immunosuppressant (see entire document, for instance column 2, lines 12-18). Guglielmotti teaches the immunosuppressant is typically prednisolone, methylprednisolone, or prednisone (see entire document, for instance, column 2, lines 5-11). Guglielmotti specifically identifies

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prednisone as being useful, and exemplifies a dosage of 5 mg (see entire document, for instance column 2, lines 48-51 and column 4, lines 1-3), wherein the composition of Guglielmotti can be in the form of coated tablets which comprise excipients and coloring agents (see entire document, for instance column 2, lines 58-62).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize the medicaments, bindarit and prednisone (5mg), as the medicaments of Spence. One would have been motivated to do so since Spence teaches that the medicament can be any desired medicament, wherein Guglielmotti teaches clear motivation for why one would desire bindarit and prednisone which includes the numerous diseases that can benefit from the delivery thereof. There would be a reasonable expectation of success in the use of the medicaments of Guglielmotti in the delivery system of Spence since Spence teaches that any desired medication can be utilized, wherein further Guglielmotti teaches that the medicaments of Guglielmotti can be in the form of a coated tablet and can comprise excipients and coloring agents.

Conclusion

No claims allowed. All claims rejected. No claims objected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TREVOR M. LOVE whose telephone number is (571)270-5259. The examiner can normally be reached on Monday-Thursday 7:30-5:30.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached on 571-272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TL

/David J Blanchard/
Primary Examiner, Art Unit 1643